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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2018-0043]

Changes to the *Salmonella* and *Campylobacter* Verification Testing Program: Revised Categorization and Follow-up Sampling Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing and requesting comments on revised categorization and follow-up sampling procedures relative to pathogen reduction performance standards. FSIS will proceed with web-posting individual establishments' category status for pathogen reduction performance standards for *Salmonella* in raw chicken parts and not-ready-to-eat (NRTE) comminuted chicken and turkey, as previously announced, and updating individual poultry carcass establishments' category status in November. However, the category status reported will be based on FSIS sample results during the 52-week window ending the last Saturday of the previous month, rather than on results during the last 13 completed 52-week windows. At the same

time, FSIS will no longer include follow-up sampling results as part of the moving window when determining establishment category status. Finally, FSIS will update the individual establishments' category status on its website on a monthly basis and will maintain the last six months of historical establishment-specific categorization data on the website, as it becomes available, using the revised categorization procedures announced in this notice.

FSIS intends to use the revised categorization procedures for all establishments subject to a pathogen reduction performance standard for *Salmonella* or *Campylobacter*, including beef and pork establishments, in the future. FSIS will announce any expanded use of the revised procedures in the **Federal Register** and will request public comment.

FSIS will proceed with implementing the changes on the date announced in this notice. However, FSIS is seeking comments on the changes as part of its effort to continuously assess and improve the effectiveness of Agency policy.

DATES: Submit comments on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. On

November 23, 2018, FSIS will:

- Web-post individual establishments' category status for pathogen reduction performance standards for *Salmonella* in raw chicken parts and NRTE comminuted chicken and turkey and update individual poultry carcass establishments' category status based on FSIS sample results during the 52-week window ending on October 27, 2018;
- Discontinue including follow-up sampling results as part of the moving window when determining category status for that establishment; and
- Begin updating individual establishments' category status on the FSIS website on a monthly basis using the revised procedures announced in this notice.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions

at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2018-0043. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202) 720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly packaged and labeled. In support of this mission, FSIS began its *Salmonella* verification testing program with the final rule entitled "Pathogen Reduction; Hazard Analysis and Critical Control Point Systems" (PR/HACCP Rule), published on July 25, 1996 (61 FR 38805). Among other things, the PR/HACCP Rule established *Salmonella* pathogen reduction performance standards for establishments that slaughter selected classes of food animals and/or that produce selected classes of raw ground products. FSIS continues to use the pathogen reduction performance standards to ensure that eligible establishments are consistently controlling or reducing harmful bacteria on raw meat and poultry products.

FSIS began posting individual establishment categories for *Salmonella* performance standards for poultry carcasses in May 2016.¹ In November 2016, FSIS temporarily suspended the web posting of category status for individual carcass establishments to analyze the effect of the use of FSIS's

¹ <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/establishment-categories-cu>

new neutralizing Buffered Peptone Water on the *Salmonella* performance standards and to assess the implementation of follow-up sampling at Category 3 poultry carcass establishments (that is, establishments not meeting the standard). Upon conclusion of these analyses, FSIS resumed web posting of individual establishments' category status for *Salmonella* performance standards for poultry carcasses on January 23, 2018. As discussed in the February 11, 2016 **Federal Register** notice, data support that public posting of establishment performance encourages establishments to make changes to address *Salmonella* (81 FR 7285).

FSIS also explained in the February 2016 **Federal Register** notice how it would assess establishment performance using a moving window of FSIS sampling results in poultry establishments subject to a pathogen reduction performance standard. For all establishments, FSIS defines an individual window as the results from FSIS sampling over 52 consecutive Sunday-to-Saturday weeks. Under the policy in the February 2016 **Federal Register** notice, FSIS used for each window all FSIS samples taken in any given week, including follow-up samples collected by FSIS to verify the adequacy of corrective actions taken by an establishment

that was not meeting a performance standard. The category assigned to an establishment has been based on results in the 13 most recent completed 52-week windows, which includes 64 weeks of data. If the establishment exceeded the performance standard in any of the last 13 completed windows, it was assigned to Category 3, i.e., designated as not meeting the standard (81 FR at 7287). Thus, under this policy, establishments that implemented effective corrective actions and demonstrated sustained process control remained in Category 3 until all 13 windows registered Category 1 or 2, i.e., reflected that the establishment was meeting the performance standard over 13 52-week windows.

Although assessing 13 windows of data reduces the chance that an establishment's category status will change when there is no actual improvement in process control and improves FSIS's ability to assign small and very small establishments to a category,² an establishment's category status may not necessarily reflect the current conditions

² Since there are 13 52-week windows, an establishment has 13 chances to be categorized. With fewer windows, fewer establishments may be categorized. This is because there is a minimum number of samples needed to assess process control for each product class by pathogen (e.g., the minimum number of samples for *Salmonella* in broiler carcasses is 11).

in an establishment that has taken effective corrective actions. Under the current policy, even if an establishment has been in category 1 for multiple weeks, if it was in category 3 in any one of the last 13 52-week windows, FSIS would designate that establishment as category 3.

Representatives from the poultry industry have raised these concerns to FSIS. In response to their concerns and internal concerns about whether the 13-window categorization procedure is accurately indicating the state of an establishment's process control following implementation of corrective actions, FSIS has reevaluated its policies.

Changes to Categorization Procedure

With the goal of encouraging sustained improvements in process control while still accurately reflecting current conditions in the establishment, FSIS has considered a full range of alternatives to the current 13-window categorization procedure. Based on the evaluation of available data, FSIS concluded that reducing the number of completed 52-week windows assessed from 13 to one (1) is the best means to accomplish this goal. This approach will continue to minimize the effect of seasonal variation in

pathogen incidence on category status, while providing a pathway for establishments to improve their category status after implementing effective corrective actions. This approach is far less complex than the current 13-window categorization procedure. This approach will not have an effect on public health

FSIS anticipates that the revised categorization procedure could reduce category stability over time, meaning that establishments could experience more frequent changes in category status. Using data analyzed over a 20-month period (from January 2017 to August 2018), FSIS compared the current 13-window categorization procedure to the revised 1-window categorization procedure and found the effect on stability of the revised categorization procedure for establishments was minimal for most establishments. The largest effect on stability was observed with establishments producing raw chicken parts. For these establishments, the number of establishments assigned to Category 3 two or more times over the 20-month period increased, from six establishments (1 percent) under the current 13-window categorization procedure, to 49 establishments (12 percent) using the revised 1-window

categorization procedure. This finding could be due to the variability in the incidence of *Salmonella* in raw chicken parts compared to other products.

In addition, available data suggests the revised categorization procedure has the greatest potential to reduce the time an establishment spends in Category 3 when it has taken effective corrective actions. FSIS evaluated the impact of the revised categorization procedure for eligible establishments producing chicken carcasses from January 2017 to August 2018. Under the revised procedure, the 75th percentile for time spent in Category 3 for these establishments was 156 days, compared to 234 days under the current 13-window categorization procedure. This means that with the revised categorization procedure, 75 percent of these establishments remained in Category 3 for 156 days or less, compared to 234 days or less for the current 13-window categorization procedure.

On November 23, 2018, FSIS will post on its website the category status of individual establishments for pathogen reduction performance standards for *Salmonella* in raw chicken parts and NRTE comminuted chicken and turkey, as

previously announced,³ and updated individual poultry carcass establishments' category status. However, the category status reported will be based on FSIS sample results, excluding any follow-up sample results, during the 52-week window ending on October 27, 2018, rather than on sample results, including follow-up sample results, in the last 13 completed 52-week windows. FSIS will categorize these establishments following the criteria below:

- **Category 1:** Establishments that have achieved 50 percent or less of the maximum allowable percent positive during the most recent completed 52-week moving window.
- **Category 2:** Establishments that meet the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most recent completed 52-week moving window.

³ On May 4, 2018, FSIS announced an initial posting date for raw chicken parts and NRTE comminuted poultry products of "October 2018" in the *Constituent Update*. Subsequently, the date was extended to "November 2018...after Thanksgiving." Webinar presented to stakeholders with new date is available at <https://www.fsis.usda.gov/wps/wcm/connect/f059169f-5cb3-4ae5-9388-7de79b9fa217/Salmonella-Categorization-Webinar061318.pdf?MOD=AJPERES>

- **Category 3:** Establishments that have exceeded the maximum allowable percent positive during the most recent completed 52-week moving window.

Thereafter, FSIS will update category status on the FSIS website for these establishments using the revised categorization procedures on a monthly basis based on the category status for the 52-week window ending the last Saturday of the previous month.

To be clear, the pathogen reduction performance standards for *Salmonella* in young chicken or turkey carcasses, raw chicken parts, and NRTE comminuted chicken and turkey products, and the minimum number of samples needed for FSIS to assess whether these establishments meet the standards have not changed.

Follow-up Sampling

FSIS also examined the role of follow-up samples established in the February 2016 **Federal Register** notice, where FSIS stated that follow-up samples would count towards the samples collected as part of the moving window for that establishment. FSIS established that policy because we thought it would more quickly assess whether establishments have reduced variability of process control.

FSIS evaluated follow-up sampling results from establishments producing chicken carcasses since January 2017, when this sampling was introduced. The Agency concluded that follow-up sample results did not significantly influence the amount of time that establishments resided in Category 3 and that FSIS could effectively categorize establishments without including Agency follow-up sampling results.

Therefore, starting with the data posted on November 23, 2018, FSIS will no longer include follow-up sampling results as part of the moving window when determining establishment category status. FSIS's evaluation of its follow-up sampling strategy is ongoing. Potential changes being considered include the timing and number of follow-up samples collected. While these and other potential changes are considered, FSIS will continue conducting follow-up sampling in establishments that do not meet a *Salmonella* pathogen reduction performance standard. However, to reduce the potential for redundant FSIS resource expenditure in establishments that undergo multiple changes in category status over a short period of time, FSIS will consider

limiting the number of follow-up sets of samples⁴ and Public Health Risk Evaluations initiated when an establishment exceeds a pathogen reduction performance standard to no more than once every 120 days. The justification for this is that an establishment is provided 30 days to implement corrective actions prior to assignment of the follow-up sample set in the Public Health Information System. Establishments then have 90 days to validate any changes to their Hazard Analysis and Critical Control Point (HACCP) system after being notified that it is in Category 3.

Additional information

In addition to posting establishment-specific category status information, FSIS intends to begin maintaining historical individual establishment categorization data on the FSIS website. FSIS estimates providing six months of historical categorization data for each establishment would be useful for those who want to make business decisions using the information. FSIS currently only maintains the most recent monthly individual establishment posting on its web site. FSIS will also continue providing aggregate sampling results relative to categories for establishments

⁴ Depending on production volume, 16 or 8 samples would be collected as part of a follow-up sample set.

producing young chicken or turkey carcasses, raw chicken parts, or NRTE comminuted chicken and turkey products.⁵ FSIS will continue to maintain the most recent year of aggregate data reports on its website as well.

FSIS intends to use the revised categorization and any follow-up sampling methodology, as well as the web posting procedures announced in this notice, for any establishment subject to a pathogen reduction performance standard for *Salmonella* or *Campylobacter* at a future time, including beef and pork establishments. FSIS will announce any expanded use of the revised procedures in the **Federal Register** and will request public comment.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at:

<http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is

⁵ Available at <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/aggregate-data>.

used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service, which provides automatic and customized access to selected food safety news and information. This service is available at:

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E-mail: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Carmen M. Rottenberg,

Administrator.

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